



MESSENGER

Published quarterly by MedDRA MSSO for our subscribers

What's New in Version 10.0

By Dr. Maya Nair
Medical Officer

MedDRA Version 10.0 was a milestone version that included routine dictionary maintenance activities as well as some significant developments. This article summarizes details that are included in the MedDRA "What's New" supporting document. This and other supporting documents are available for subscribers on the MedDRA

Web site Downloads section for Version 10.0.

Even though it was a complex change release, MedDRA Version 10.0 was smaller than previous releases. There were 13 complex change proposals posted on the MSSO Web site for subscriber comments which resulted in 17 implemented changes at the higher grouping levels. A significantly higher number of change requests was suspended pending further resolution. Some of these included requests to align ICD-9 concepts that exist in MedDRA.

The issue of double spaced LLTs in MedDRA led to a number of renamed LLTs. These inherited terms incorporated double spaces and were resolved either by amending them

with a hyphen (-) or renaming them to reflect only single spaces (see double spaced article in this publication).

The table captures the total number of terms at each level in MedDRA Version 10.0.

As part of ongoing activities in MedDRA, the Blue Ribbon Panel 5 meeting on the feasibility study for HLT/HLGT grouping terms resulted in several constructive recommendations. The details on these can be found on the MSSO Web site: www.meddramsso.com/MSSOWeb/activities/blueribbonpanels.htm.

Number of terms: MedDRA Version 10.0

System Organ Classes (SOC)	26
High Level Group Terms (HLGT)	332
High Level Terms (HLT)	1,682
Preferred Terms (PT)	17,719
Lowest Level Terms (LLT) *	47,428

* Does not include PTs

Standardised MedDRA Queries (SMQs) have undergone a robust growth with nine new SMQs added this version. For more detailed information on the status of SMQs or to download SMQs, go to: www.meddramsso.com/MSSOWeb/SMQ/index.htm.

Lastly, there were notable differences in the types of change requests received from subscribers in MedDRA Version 10.0. There was a particular emphasis placed on the latest types of medical and therapeutic developments happening worldwide. These included: new procedures, vaccine concepts, new diagnostic concepts, and newer nomenclature of existing terminologies.

Last Distribution of MedDRA CD-ROM

The MSSO is discontinuing the distribution of MedDRA on CD-ROM. Effective 1 September 2007, and concurrent with the Version 10.1 release, all current subscribers will be given access to MedDRA via internet file download.

For those subscribers who currently receive MedDRA in CD-ROM format, MedDRA Version 10.0 was the last provided.

Subscribers wishing to have a CD-ROM copy of MedDRA for use within their organizations may work with their IT staff to copy the files onto CD-ROM once downloaded from the MSSO Web site.

Should you have questions, please contact the MSSO Help Desk at mssohelp@ngc.com or 1-877-258-8280 (AT&T Worldwide).



Regulatory Authorities – Their View of SMQs

By Dr. Patricia Mozzicato
Medical Officer USA

Recently, the “Guidelines on Pharmacovigilance for Medicinal Products for Human Use” (commonly known as “Volume 9A”) was published by the European Commission.

The guideline makes reference to Standardised MedDRA Queries (SMQs) as follows: “Standardised MedDRA Queries (SMQs) may be used for signal detection and the use of SMQs is recommended in order to retrieve and review cases of interest where signals are identified from adverse reaction databases.”

Several other regulatory authorities, through their involvement with the CIOMS Working Group for SMQs, are also interested in the development and use of SMQs. The MSSO contacted three EU regulators to obtain insight on how they intend to use SMQs.

EMEA (EUROPEAN MEDICINES AGENCY)

The EMEA is implementing SMQs in the EudraVigilance (processing network and management) System. A pilot phase is underway to determine how best to apply SMQs in a pharmacovigilance environment.

SMQs can be used in the system whenever the definition of a reaction term is requested. The system is able to operate with multiple SMQs, and

each SMQ may contain a hierarchy of up to five levels. The implementation supports the query scope, and it is possible to select the “broad” or “narrow” search facility for each query. In the Data Analysis System, it is also possible to combine SMQs with the standard MedDRA hierarchy (primary or secondary SOCs).

In addition to the use of SMQs in the European database, their use has also been proposed in Risk Management plans. Annex 1 to the Annex C of the Risk Management plan is the electronic template that contains the core information from the plan. This electronic template can be loaded into EudraVigilance so that stakeholders may monitor targeted medical events or other safety aspects.

The option to specify a MedDRA level is given so that the monitoring process may be performed on any MedDRA term level. For example, a Preferred Term (PT) or an SMQ may be specified. Consideration must be given to the fact that different results can be achieved from searching a database using an SMQ as opposed to a PT or an HLT. It is also subject to individual opinion which PTs to include in the risk management template as this may lead to inconsistency.

It is possible that the use of SMQs in this area could reduce the inconsistency but this is still under discussion.

The role of SMQs in signal detection is also currently under investigation at EMEA.

BfArM (GERMAN REGULATORY AUTHORITY)

As of November 2006, BfArM had not yet implemented SMQs. They anticipate a software update to their database in the next few months that will provide the necessary functions for SMQ use.

The tools BfArM envisions will provide a list of PTs with which a database search can be performed, similar to lists of terms that are generated when using HLTs, HLGs, or SOCs. SMQ algorithms will be addressed similarly but search results, that is, safety report identifiers received using the different term lists, will require an “intersect” statement on the database level to get only those reports in which all conditions defined by an SMQ algorithm are fulfilled.

Once the technical platform is in place, BfArM has identified the following areas for SMQ use:

- Routine database queries: whenever an SMQ is suitable to address a specific question, it will be used. BfArM believes this approach will regularly lead to more comprehensive searches and more reproducible results compared to the individual term selection by a MedDRA user.

- Signal detection: the next intended step is incorporating SMQs into signal detection tools. Due to the granularity of MedDRA, potential signals may disappear when focusing on separate PTs only. SMQs sum up a variety of terms linked to a certain medical condition of interest so that they may be able to detect a signal which might not be seen using PTs alone.

- Data presentation: whenever BfArM receives requests from healthcare professionals concerning a specific type of adverse reaction, SMQs may be used for database searches as well as for data presentation. SMQ descriptions provided by MSSO may be added so that the inquirer can understand the rationale behind the results provided.

- Requests to companies to use SMQs to find relevant cases for specific questions: in that context, SMQs have a

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MedDRA® MSSO
VAR1/7B/MSSO
12011 Sunset Hills Road
Reston, VA 20190-3285
USA

TOLL FREE INTERNATIONAL
877.258.8280 (AT&T)

DIRECT
703.345.7799 (USA)

FAX
703.345.7791 (USA)

MSSO-DI-7184 1.0.0

ACKNOWLEDGEMENTS

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Special Search Category (SSC) Files: No Longer a Part of the MedDRA Version Release

Special Search Categories (SSC) were retired with the release of MedDRA Version 10.0. They did not appear on the CD-ROM or Internet File Download for MedDRA Version 10.0.

MedDRA Version 9.1 was the last version to include SSCs, and the SSC files (spec.asc and spec_pt.asc) are now archived and available from the MSSO Web site at www.meddramsso.com/MSSOWeb/term_maint/index.htm.

For subscribers uploading the complete set of MedDRA ASCII files to the MedDRA Browser, please be aware that

there will only be a total of 12 files (instead of 14) to upload. These 12 files include the MedDRA terminology and the Standardised MedDRA Queries (SMQ) files.

Please remember that the SSCs were based upon linkages at the PT level and that in each version subsequent to MedDRA Version 9.1, PTs may be demoted, and new PTs may be added to better represent the PT concept.

Therefore, if you use the archived SSC files with a version other than 9.1, there may be terms that are no longer linked to the SSC as they were in Version 9.1.

Regulatory Authorities – Their View of SMQs

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particular advantage, especially if more than one company is involved in an overall analysis of a specific safety issue. Companies may also feel free to use suitable SMQs in Periodic Safety Update Reports or Annual Safety Reports.

MHRA (UK REGULATORY AUTHORITY)

MHRA is currently making major changes to its IT systems including its pharmacovigilance database. Therefore, SMQs have not yet been loaded into the pharmacovigilance database. In the MHRA's previous database, Special Search Categories (SSCs; now "retired" by MSSO as of MedDRA Version 10.0) had been embedded in the query tool which is used for searching the database (a modified version of Business Objects).

Currently, MHRA uses SMQs on an ad hoc basis for searching the database by creating a comma separated file

(CSV) from the ASCII information; this is loaded into the Business Objects query tool. Once MHRA has made the final changes to its database, they plan to load the SMQs into Business Objects in the same way that the SSCs were loaded. MHRA does not anticipate a need to make major changes to their database to accomplish this because MedDRA is derived from a previous MHRA medical terminology.

SUMMARY AND CONCLUSION

SMQs are still on the "uptake" by industry and regulatory authorities, but clearly, some major health authorities are in the process of planning for their widespread use in the future. For more information on SMQs, please visit the MSSO Web site at www.meddramsso.com/MSSOWeb/SMQ/index.htm.

The MSSO gratefully acknowledges our friends at EMEA, BfArM, and MHRA for providing information about their implementation of SMQs.

Please visit us at the Drug Information Association Annual Meetings

19th Annual Euro DIA Meeting

Booth Number 128
Vienna, Austria
26-28 Mar 2007

US DIA Annual Meeting

Booth Number 817
Atlanta, Georgia
17-21 Jun 2007

For more detailed information, go to: www.meddramsso.com/MSSOWeb/activities/conf.htm

PLEASE JOIN US FOR AN INTERNATIONAL MEDDRA USER GROUP MEETING

EU MedDRA User Group Meeting

Vienna, Austria
29 Mar 2007

US MedDRA User Group Meeting

Atlanta, Georgia
21 Jun 2007

Subscribers may register today at:
www.meddramsso.com/MSSOWeb/activities/usrmtg.htm

WE WANT YOUR FEEDBACK!

PLEASE CONTACT US

TOLL FREE INTERNATIONAL 877-258-8280 (AT&T)

DIRECT: 703-345-7799 FAX: 703-345-7791

E-MAIL: MSSOHELP@NGC.COM

**IF YOU WANT TO BE ADDED TO THE MAILING LIST, PLEASE VISIT THE
WEB SITE WWW.MEDDRAMSSO.COM OR E-MAIL US.**



MedDRA OPEN TRAINING

MARCH – JUNE 2007

The training schedule is periodically updated. Please access www.meddramsso.com for updates.

EUROPE

	FULL SCOPE	CODING WITH MedDRA	ADVANCED CODING	MedDRA: SAFETY DATA ANALYSIS & SMQs
APRIL			London, UK 25 April	London, UK 25-26 April
MAY	Frankfurt, Germany 9 May		Frankfurt, Germany 10 May	

NORTH AMERICA

MARCH	Chicago, IL USA 6 March		Chicago, IL USA 7 March	
APRIL	Seattle, WA USA 19 April			Seattle, WA USA 20 April
MAY	Chantilly, VA USA 2 May		Chantilly, VA USA 3 May	Chantilly, VA USA 3-4 May
JUNE	San Francisco, CA USA 6 June		San Francisco, CA USA 7 June	

WEBINARS

Use of Medication Error Concepts in MedDRA 11 April 15 May	MedDRA for Statisticians & Programmers 20 April 12 June
MedDRA for the IT Professional 25 April	MedDRA Coding Basics 22 March

NEW SUBSCRIBER TRAINING SESSIONS

SPRING 2007	Seattle, WA USA 18 April	Chantilly, VA USA 1 May	Frankfurt, Germany 8 May	San Francisco, CA USA 5 June
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REGULATOR TRAINING SESSIONS

SPRING 2007	London, UK — 24 April	Silver Spring, MD USA — 21-22 May	Ottawa, Canada — TBD
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Registration for all sessions can be accomplished through the MSSO Web site
www.meddramsso.com AT&T toll free number: (877) 258-8280



MedDRA Course Descriptions

ADVANCED CODING: CODING CONVENTIONS AND THE MedDRA “POINTS TO CONSIDER” DOCUMENT (1/2-DAY SESSION)

This half-day course provides experienced MedDRA users with a basis for understanding the importance and utility of coding conventions as they pertain to the conversion of legacy data to MedDRA and for new data received post-conversion. Participants will be given a thorough overview of the MedDRA Term Selection: Points to Consider document and will see examples of challenging verbatim terms to code by applying the principles described in the document. Finally, participants will take a final “test” to assess their knowledge and understanding of what had been presented in the course.

CODING WITH MedDRA (1-DAY SESSION)

In addition to lecture instruction providing a basic understanding of the scope, structure, and rules of MedDRA, trainees receive ‘hands-on’ experience coding challenging verbatim terms to demonstrate their knowledge of MedDRA’s structure and rules.

MedDRA: SAFETY DATA ANALYSIS AND SMQs (1-DAY SESSION)

Combines the materials of two former MedDRA courses, “MedDRA: Interpreting Data and Query Development” and “Standardised MedDRA Queries (SMQs) Primer,” into a full-day class designed to provide an overview of the features of MedDRA that relate to the analysis and retrieval of MedDRA encoded data.

THE FULL SCOPE OF MedDRA (1 1/2-DAY SESSION)

Provides a basic understanding of the scope, structure, and rules of MedDRA, reviews the System Organ Classes that are unique to MedDRA, and explains how MedDRA was developed. With electronic regulatory submissions now in place, it is imperative for your organization to understand the rules, usage, and practices of the only international, clinically validated, maintained medical terminology for biopharmaceutical regulatory purposes. The course illustrates coding examples as they pertain to the scope of MedDRA, the differences between older coding terminologies and MedDRA, tools that support coding, and a hands-on approach to coding verbatims and narratives with MedDRA.

Webinar Training Topics

Course descriptions may be found at www.meddramsso.com

MEDDRA CODING BASICS (ONE 1 1/2 HOUR WEBINAR SESSION)

Coding Basics provides a brief overview of MedDRA; introduces the “MedDRA Term Selection: Points to Consider” document; uses coding examples to illustrate general principles of coding; and provides trainees with a set of coding “pearls” based on the broad coding experience of MSSO’s medical personnel.

MEDDRA FOR STATISTICIANS AND PROGRAMMERS (ONE 2-HOUR WEBINAR SESSION)

The Stats and Programmers webinar provides a brief overview of MedDRA and focuses on the practical use and application of MedDRA for data presentation, retrieval, and analysis (including use of SMQs) from a statistical programming perspective.

MedDRA FOR THE IT PROFESSIONAL (WEBINAR PRESENTATION IN TWO 2-HOUR SESSIONS)

MedDRA will soon become a regulatory requirement. Most organizations

are taking advantage of the time now to develop a MedDRA implementation strategy. The IT systems provide the infrastructure for this process. MedDRA for the IT Professional covers MedDRA implementation issues from the IT perspective and identifies the key points to consider for existing or new

systems, data issues, MSSO interaction, and electronic submissions.

USE OF MEDICATION ERROR CONCEPTS IN MEDDRA (ONE 1 1/2 HOUR WEBINAR SESSION)

The Med Errors webinar provides a

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Training Modules Available for Download

DATA QUALITY, CODING AND MEDDRA TRAINING MODULE (FREE OF CHARGE — SUBSCRIBER LOG-IN REQUIRED)

This course provides a general discussion of the importance of collecting quality data and the role of MedDRA. The target audiences are investigators, study coordinators, and pharmaceutical company and CRO personnel including physicians, CRAs, safety officers, statisticians, programmers, and data managers. The presentation has a “place holder” slide for subscribers to customize the course with their own company-specific data collection and reporting conventions. This feature can be a very useful adjunct for investigator training.

NEW SUBSCRIBER SESSIONS: The MSSO offers free training for new subscribers at the Basic, Core 0, and Core 1 subscription levels. Eligible organizations receive two training credits which can be used to attend specific new subscriber training sessions.

REGULATOR SESSIONS: The MSSO offers free training to regulators. Regulators receive two training credits per year.

All of the above topics are available for onsite presentation



Double-Spaced Terms Issue Resolved in MedDRA 10.0

By Jim Mundell

Recently, it was reported that certain computer systems strip out all spaces when loading or searching terms, and as a result, six MedDRA terms keep generating “duplicate-errors” messages.

To understand the basis of this problem and the implemented solution, it is necessary to review a little of the history of double-spaced terms in MedDRA.

There have been 20 MedDRA terms with embedded double spaces since the first MSSO release of MedDRA (Version 2.1). All of these terms came to MedDRA from another terminology.

The existence of these double-spaced terms was first discovered early on when subscribers reported problems doing exact match queries. For example, LLT *Pancreatic secretion decreased* (which contains a double space) could not be found when doing a query using “Pancreatic secretion decreased” because of the extra space in the MedDRA term.

All of these double-spaced terms have been set to a non-current status for many years. The six terms which generated the above stated error condition, however, are commonly used terms, and subscribers requested useable versions of these six terms.

Because these double-spaced terms were from a different terminology, the MSSO terminology group was directed not to modify them. Instead, the MSSO added six new terms without the double spaces.

The MSSO no longer believes that there should be a

restriction regarding the modification of these double-spaced terms.

SOLUTION — PART 1

To correct the six terms related to the “duplicate-error” problem, the MSSO has removed each double space from the non-current term and replaced it with a hyphen (-). This will resolve the reported conflict when all spaces are stripped. These terms still remain non-current in MedDRA Version 10.0.

Below is a sample term and the corrected version of each term as it appears in MedDRA, Version 10.0:

Version 9.1 - 10048484 *Proteinuria aggravated*
Version 10.0 - 10048484 *Proteinuria-aggravated*

SOLUTION — PART 2

The remaining 14 double-spaced non-current terms have no additional exact matching terms. To prevent any future confusion with queries or loading processes, the MSSO has modified these terms by reducing the double space to a single space.

Below is a sample term and the corrected version of the term as it appears in MedDRA, Version 10.0:

Version 9.1 - 10034190 *PDA Repair patent ductus arteriosus*
Version 10.0 - 10034190 *PDA Repair patent ductus arteriosus*

Please visit the Announcements section of the MSSO Web site for a complete list of corrected double spaced terms at www.meddramssso.com/MSSOWeb/announcements_feedback/subscriber_announce.htm.

TERMINOLOGY TIPS

The MSSO is introducing a new “Terminology Tips” column in this edition of the Messenger. The purpose is to hopefully make the change request process easier for you. In this first edition, we address two topics.

Did you know?

- There is no need to submit a separate change request for the addition of an identical LLT when you have already requested the term as a PT. The MSSO will automatically add the identical LLT.

- If a term has a British English or an American English spelling variant, there is no need to submit a separate change request, as the MSSO will automatically add the appropriate variant.

This feature is driven by trends and observations made by the MSSO. However, we welcome any topics or questions that subscribers may wish to address in future installments. Please submit topics or questions to MSSOhelp@ngc.com with “Terminology Tips” in the subject line.

Webinar Training Topics

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brief overview of MedDRA and focuses on the medication error concept descriptions drafted by the FDA and the MSSO. Practical examples of coding medication errors are included.

WHAT'S NEW IN MedDRA (ONE 1 1/2-HOUR WEBINAR SESSION)

The What's New In MedDRA webinar is designed to provide information on changes incorporated into each new version release and is scheduled to coincide with the corresponding version release.